K100790

510(k) Summary
COULTER® LIN-X Linearity Control

1. **Submitted By:**

Lourdes Coba
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
11800 SW 147 Avenue, M/C: 31-B06
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DEC 21 2010

2. **Date Submitted:**

March 19, 2010

3. **Device Name(s):**

3.1 **Proprietary Names**

COULTER® LIN-X Linearity Control

3.2 **Classification Name**

Hematology quality control mixture
(21 CFR § 864.8625)

4. **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® LIN-X Linearity Control (7 Levels)	COULTER® LIN-X Linearity Control (12 Levels)	Beckman Coulter, Inc.	K081641

5. **Description:**

COULTER® LIN-X Linearity Controls are stabilized human blood components whose white blood cells (WBC), red blood cells (RBC), hemoglobin (HGB) and platelets (PLT) concentrations span the instrument's reportable range. Results from repeated measurements for each concentration are compared to the established expected range to assess the instrument's calibration and verify the reportable range.

6. **Intended Use:**

COULTER® LIN-X Linearity Controls are intended to assess calibration and verify the reportable range of Coulter® Cellular Analysis Systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. Refer to Instructions for Use.

7. **Comparison to Predicate(s):**

COULTER® LIN-X Linearity Control is essentially identical to the current LIN-X Linearity Control except that it only contains Levels 1-7 of the current product and Level 6 is additionally assayed for WBC. Levels 1-5 and Level 7 have not been modified.

8. **Summary of Performance Data:**

Study	Study Design	Study Results
Open and Closed Vial Stability	Evaluated open and closed vial stability of 3 lots of Level 6 of LIN-X Linearity Control over the shelf life of the product on a DxH™ 300 and DxH™ 300C (pending 510(k) clearance K100489). The stability of Level 1-5 and Level 7 was previously cleared in K081641.	LIN-X Linearity Control demonstrated acceptable results.
Value Assignment Process	Value assignment of Level 6 WBC for each lot of LIN-X Linearity Control is determined on validated systems using specific COULTER reagents. Assigned Values are confirmed by multiple analysis of the control product.	Established process for generating assigned values for LIN-X Linearity Control.
Range Determination Process	The expected range for WBC on Level 6 was calculated by a bio-statistician based upon the assigned values and expected ranges of the WBC parameters from Levels 1-5 and 7.	Established WBC expected range for Level 6 of LIN-X Linearity Control.

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Beckman Coulter, Inc.
c/o Ms. Lourdes Coba
Staff Regulatory Affairs Specialist
11800 SW 147th Avenue
Miami, FL 33196

DEC 2 1 2010

Re: k100790
Trade/Device Name: COULTER® LIN-X Linearity Control
Regulation Number: 21CFR§864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: December 10, 2010
Received: December 13, 2010

Dear Ms. Coba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K100790

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Device Name: COULTER® LIN-X Linearity Control

Indication For Use:

COULTER® LIN-X Linearity Controls are intended to assess calibration and verify the reportable range of Coulter® Cellular Analysis Systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents. Refer to Instructions for Use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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